





Hot Topics in Pharmacy Compliance for the ASC

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The Fawks Company



About Us



MISSION: To provide 1-on-1 pharmacist support to keep ASCs on the forefront of pharmaceutical regulatory compliance.

VISION: To simplify compliance



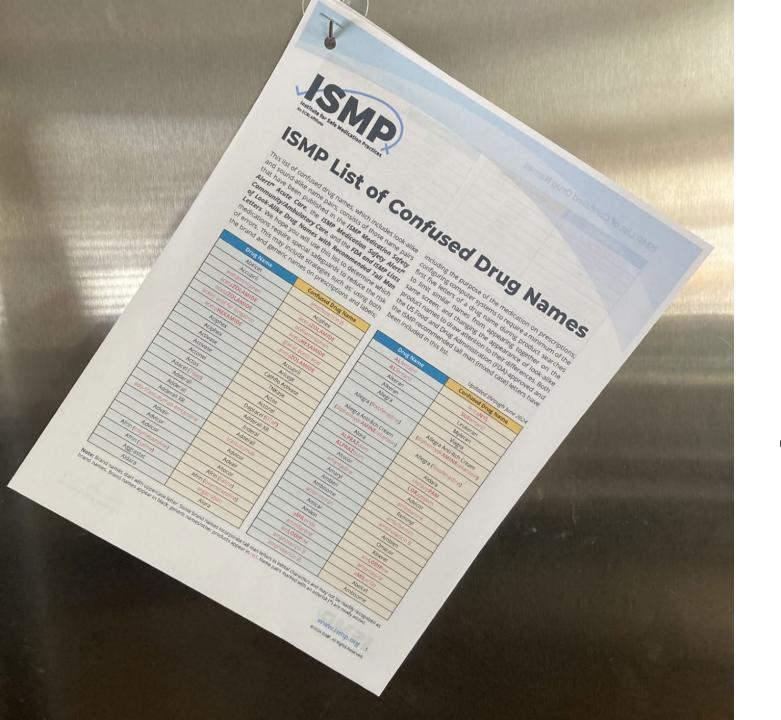
Outline

- List of Confused Drug Names and High Alert Medication Process
- Medication Waste
- 3 USP <797> and USP <800>
- 4 csos



- Facility Specific
- Obvious at ALL medication storage sites
- Denoted throughout





Facility hangs
14-page ISMP
master list in
the med room...



POVConsultant Pharmacist

Facility Specific

High Alert Medications					
Adrenergic Agonists	Insulin				
ePHEDrine EPINEPHrine	Huma LOG Humu LIN				
Phenylephrine	Moderate Sedation Agents				
Adrenergic Antagonists	D <mark>iazepa</mark> m				
Labetalol Metoprolol	Midazolam LORazepam				
Esmolol	Opioids				
Anesthetic Agents					
Propofol Ketamine	oxyCONTIN oxyCODONE morphine				
Antiarrhythmics	oxyCODONE				
Amiodarone	HYDROcodone				
Antithrombotic Agents	HYDROmorphone Fentanyl Demerol				
Heparin					
Hypertonics/ Electrolytes					
	Paralytics				
Dextrose 50%	Rocuronium Succinylcholine				
Magnesium Sulfate 50% Potassium Chloride	Contrast				
Sodium Bicarbonate	Omnipaque				
	Vesicant				
	Promethazine				

Drug Name	Confused Drug Name		
ce FAZ olin	cef TRIAX one		
DEPO-medrol	SOLU-medrol		
ePHEDrine	EPINEPH rine		
HumuLIN	HumaLOG		
HYDROcodone	oxyCODONE		
HYDROmorphone	morphine		
ketorolac	ketamine		
flumazenil	flumazenil influenza virus vaccine		
ROPivacaine	BUPivacaine		
oxyCONTIN	NTIN OXYCODONE		
SOLU-medrol	solu-CORTEF		
rocuronium	Romazicon		



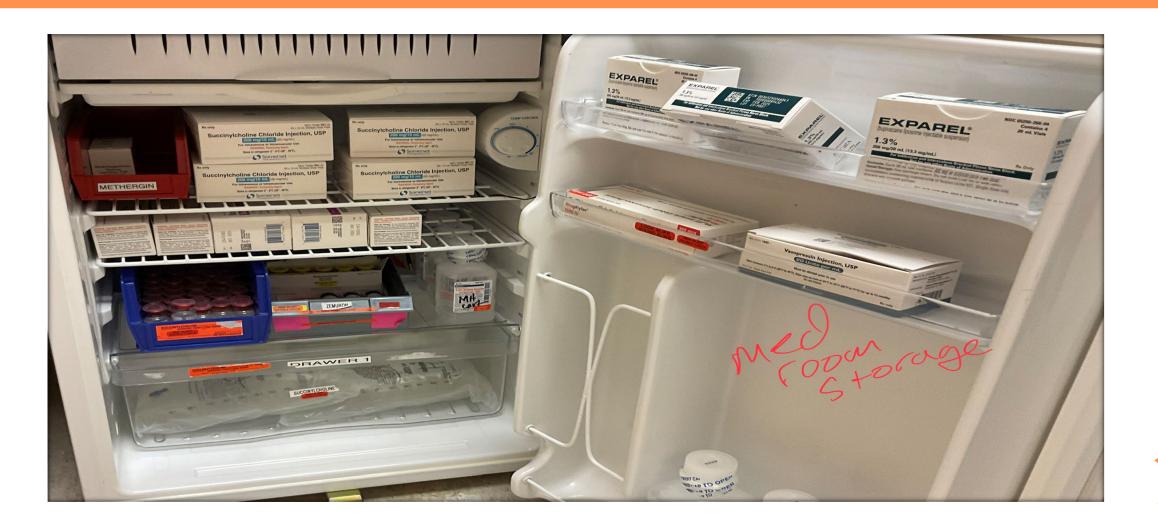
UPDATED ON 11/27/23

Med Room





Med Fridge





Crash Cart





Anesthesia Cart





Medication Waste

2

- Controlled Substances
- Non-hazardous medication waste
- Hazardous waste



Controlled Substances

FIRST

Witnessed and rendered "irretrievable"

THEN

Disposed of as non-hazardous (or hazardous) waste

NOT

Landfill trash





Non-Hazardous Medication Waste

- Majority of medication waste generated at an ASC
- No limit to amount on site at any one time







Hazardous Medication Waste

- Very small amount of waste generated
- Use "Hazardous Waste Determination" to identify medications (i.e. insulin, mitomycin, inhalers, silver nitrate, etc.)

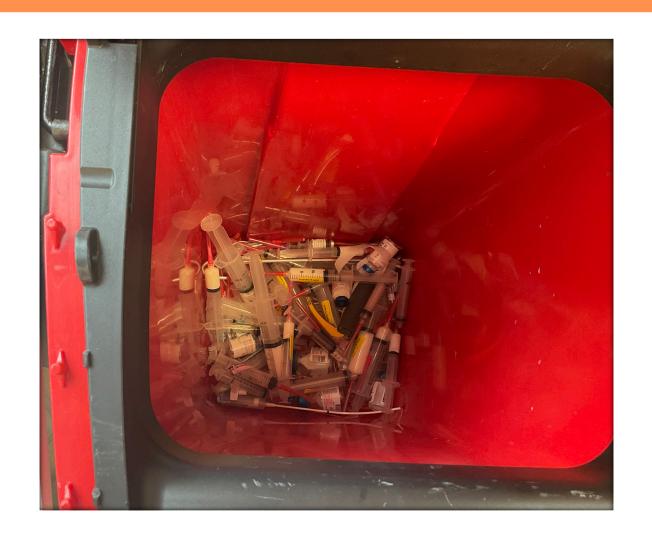




Where do you think medication waste is going?



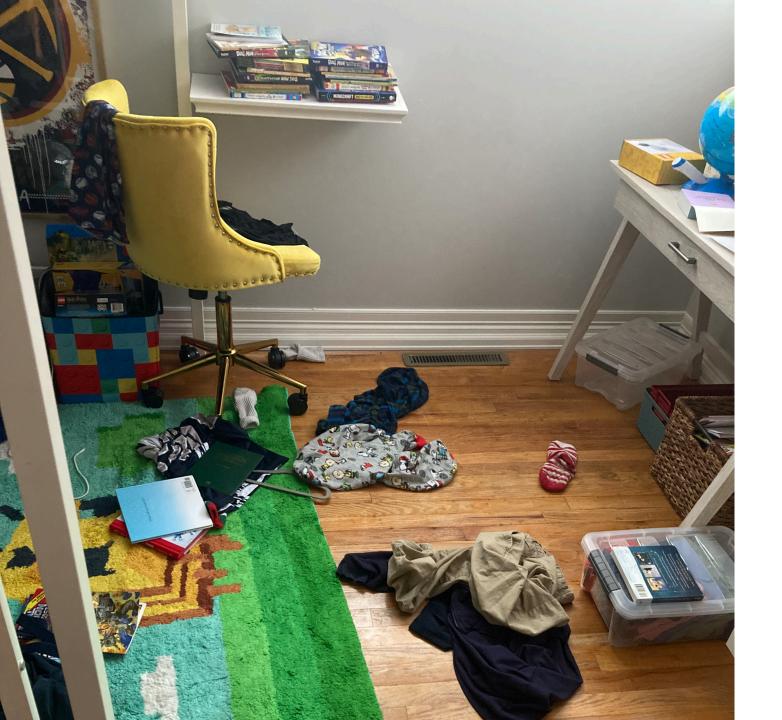
BONUS



Sharps Containers generally, *NOT* for medications







Before.



After.

USP <797> Changes

	CURRENT (2008)	REVISED (2023)					
C LESS Strict C	3 LESS Strict Changes						
Scope	Intended only for emergency situations or immediate patient administration	The emergency situation requirement has been removed The type or complexity of compounding is not specifically addressed					
Compounding Complexity	Only low-risk level CSPs (no medium-risk or high-risk level); simple transfers only						
Batch Compounding	Not intended for storage for anticipated needs or batch compounding	Batching allowed for multiple doses and/or multiple patients if all conditions are met					
# of Components	≤ 3 sterile packages	≤3 different sterile products					
# of Manipulations	≤ 2 entries into any container/package	Entries into container not defined or addressed					
Compounding Process	Compounding is a continuous process not to exceed 1 hour	Not addressed directly					
Maximum BUD 1 hour		4 hours					
Risk Level	Medium-risk and high-risk level CSPs shall not be prepared as immediate-use CSPs	Requirements for Category 1, Category 2, and Category 3 do not apply to immediate-use if all conditions are met					



USP <797> Changes













Uh-OH!



USP <800> ASC Version

- Cross reference formulary with NIOSH hazardous drug
 (HD) list Not to be confused with hazardous waste
- 2) Create assessment of risk for any identified medications
- 3) Create standard operating procedures
- 4) Training and attestation for any staff potentially in contact with HD



CSOS and **DEA**

CSOS = Controlled Substance Ordering System

Old Way

- Mailed in applications
- Passive registrant

New Way

- Online
- Active registrant



CSOS and **DEA**

New process is paperless

CSOS subscriber manual came out Feb 7th

Check the manual for details!





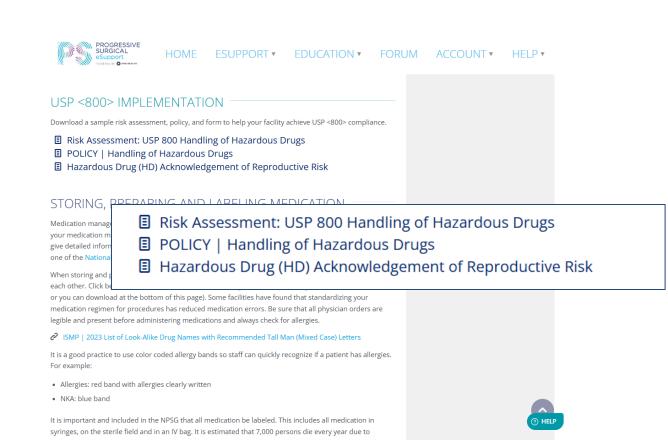
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Available to eSupport Members



eSupport > Medication Management > Medication Safety

- Risk Assessment: USP 800 Handling of Hazardous Drugs
- POLICY | Handling of Hazardous Drugs
- Hazardous Drug (HD) Acknowledgement of Reproductive Risk





Available to **eSupport Members**





- Perpetual Inventory Sheet
- Narcotic Control Sheet: OR
- Narcotic Control Sheet: Preop/PACU



FDUCATION ▼

MEDICATION MANAGEMENT

Medication Management

Controlled Substances

Overview

Eye Drops

Formulary

Compounding

MEDICATION MANAGEMENT: CONTROLLED **SUBSTANCES**

Proper management of controlled substances is essential. Mismanagement may result in noncompliance and citation's during survey. Proper management includes:

- · Policies and procedures that clearly outline processes for controlled substance management
- · A double-lock controlled substances box adhered to the wall inside a locked cabinet that remains locked
- · Maintenance of a perpetual Inventory which provides and accurate at-a-glance count of controlled
- . Documentation of a physical count at the beginning and end of each day, by 2 licensed staff members
- · A controlled substances administration record which identifies the patient, drug and dose administered, and waste documented after each patient with two licensed signatures
- · Controlled substances are prepared for each individual patient immediately prior to use and properly
- Controlled substances are never be left unattended
- . DEA 222 forms are secured.

All California ASCs to perform quarterly inventory and reconciliation functions for Schedule II drugs. If you have a consulting pharmacists this could be done when the pharmacist makes their quarterly visits

California Code of Regulations, title 16, section 1715.65, "Inventory reconciliation report of Controlled

CA Board of Pharmacy: Inventory Reconciliation Regulation FAQs

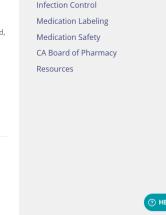


Substances"







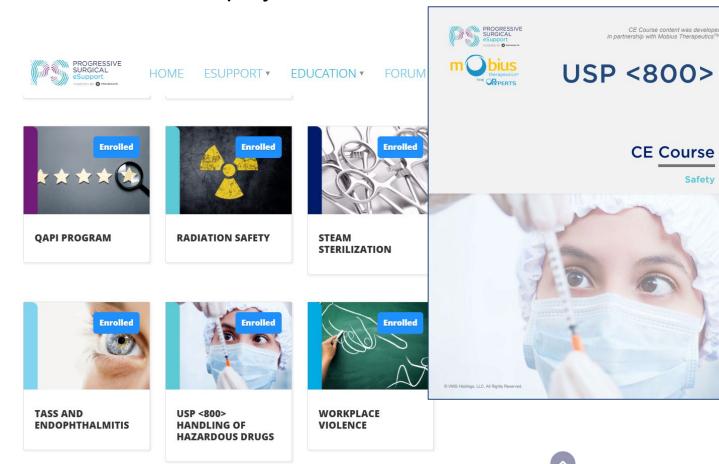


Available to eSupport Members



Education > My CE Courses > USP <800> Handling of Hazardous Drugs

Online Course for employees







The leading online membership for ASC nurse leaders who want to run a compliant, efficient, and profitable ASC with confidence.



RUNNING AN ASC CAN BE OVERWHELMING



Join our *Private*Facebook Group

A place to **connect**, **support**, and **network** with other ASC managers all over the country.



Upcoming Webinars

	DATE	()	CE	WEBINAR TOPIC	SPEAKER
	OCT 24	60		Key Strategies for Enhancing ASC Financial Health and Profitability	Vanessa Sindell MSN, BSN, RN, CAIP Nancy Stephens VMG Health
ı	NOV 10	20		Annual ASC Survey Watch Report 2025	Crissy Benze, MSN, BSN, RN VMG Health
	DEC 12	60		Life Safety Code Survey Deficiencies and Compliance Strategies	John Crowder, Jr. PG, CHFM, CFP







